



Please consider the following remarks in support of the revised claims and in connection with rejections under 35 USC 103:

REMARKS

Response to Claim Rejections under 35 USC 103:

The essential reason for rejection of basic claims 1, 3, 4, 5 by the Examiner is that the combination of Nitric Oxide (No) donors and cGMP-PDE5 inhibitors to enhance hair growth and or diminishing hair loss or alopecia was obvious to one of ordinary skill in the art by 2002 (Wallace, 6, 476, 037), because Green et al (5,358, 714) in 1994 and Garfield et al (5, 698,738) in 1997 teach Nitric Oxide (No) donors as having the ability to improve hair growth and in 2002, Wallace (6, 476, 037) teaches the synergistic effect of Nitric Oxide (No) donors like L-Arginine and Phosphodiesterase Inhibitors such as Sildenafil in the treatment of cardiac pathologies, coronary arteries vasospasms and/or the treatment of erectile dysfunction. We ask the Examiner to consider the following facts that shows Wallace was skilled in the art and he did see the synergistic effect of L-Arginine and PDE5 inhibitors and he did extend his claims to cover two distinctly different medical areas such as cardiovascular and erectile dysfunction but did not claim synergistic enhancement of hair growth in some 44 claims that he stated. We maintain that this was not an obvious claim for him, otherwise he would have stated it, as also the Examiner has acknowledged in paragraph 1 on page 2 of the latest office action (6/08/05). We respectfully ask the Examiner to consider our intricate medical points in this discussion and do not consider the Nitric-Oxide (NO) donor+cGMP-PDE5 combination as an obvious issue for hair growth because Wallace in his 44 claims on vastly different areas of medical treatment did not see the enhancing effect of the combination of NO donors and cGMP-PDE5 inhibitor on hair growth, as the Examiner has also acknowledged. Wallace was more than one of ordinary skill in the art and in fact he is an expert in the art and did not see the hair growth connection. Otherwise he would have claimed it in his 44 claims. In all of his patent references (some 12) and foreign patent references (some 5) and his technical and scientific references (some 35) there is not a single reference to hair growth. His claims are in connection with erectile dysfunction (some 9 claims), coronary vasospasm and cardiac pathologies (some 25 claims) and kits for treating erectile dysfunction ad coronary vasospasm (some 9 more claims) and has no general claim for other medical application. We maintain that if hair growth applications were obvious to him he would have claimed them. Here really the non-obvious novelty is in the use of sildenafil citrate or Viagra for hair growth that no one has proposed in the past (the acidic compound of sildenafil which he never mentions or claims because he only mentions sildenafil in his application). As the examiner also acknowledges he never claims hair growth effects of the synergy even though by 2000 he knew of the hair growth properties of minoxidil or Rogain as also disclosed by the Green (714) in 1994 and Garfield (738) in 1997, which were known to him as an expert in the field. We strongly request the examiner to reconsider the question of obviousness because even up to now no one of these experts of tremendous skill in the art has come up with the novel idea of using Viagra



for hair growth. Mr. Berko please be fair and allow us the claims.

On the 35 USC 103 rejection of our claims 1, 2, 6 and 21-23 on the basis of Wallace (037) in view of Rodgers et al (6, 747, 008) and Bazzano (5, 183, 817) and Bazzano et al (5, 514, 672) we have the following comments in addition to the fundamental comments made above:

First of all there is not a single mention of NO donors, nitric oxide donors, or PDE 5 inhibitor in Rodgers et al (008). Rodgers et al (008) does mention once or twice the word minoxidol, which I don't know what it is because it is not minoxidil. Be that as it may Rodgers et al never discuss what minoxidol does. They have not disclosed any combination of Nitric Oxide (NO) donors and cGMP-PDE5 inhibitors, as the Examiner also has acknowledged. Not only this hair growth enhancement or prevention of alopecia was not obvious to Wallace (037), it was certainly not obvious to Rodgers (008) by 2004 either. Regarding Bazzano (817) in 1993 and Bazzano et al (672) in 1996 please note that they combine a Nitric Oxide (NO) donor such as Minoxidil with Retinoids, which is kind of like vitamin A (672, column 3, lines 35-40) which are shown to cause elevated DNA synthesis in keratinocytes in cell culture and thus has nothing to do with cGMP-PDE5 inhibitors which inhibit the formation of PDE5. True that they propose the idea of enhancing the effect of Minoxidil by the addition of Retinoids but our enhancement is by the addition of cGMP-PDE5 inhibitors, which operate entirely differently from Retinoids. Please note that again Redgers et al are experts in the skill of the art and the application of sildenafil citrate to enhance hair growth was not obvious to them either as far as 2004. What is truly novel here is the application of sildenafil citrate (Viagra) for hair growth, which has not been obvious to any expert or one of ordinary skills in the art. We strongly request the examiner to be fair and reconsider his doctrine of obviousness in this case.

Having responded to each and every objection and rejection raised by the Examiner, it is believed that the patent application is now in condition for allowance, and such allowance is respectfully requested. If the Examiner has any questions or suggestions for expediting an allowance in this matter, the Examiner is invited to call the undersigned (505 975 0888) collect.

The Commissioner is authorized to charge any required fees, which may be required during the entire pendency of the application.

Respectfully submitted,

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